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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,493	08/21/2003	Eric Rose	50634-BA	9464

7590 01/30/2006

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New York, NY 10036

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/646,493

Applicant(s)

ROSE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9,38,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 38,43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2006 has been entered.
2. Applicant's election with traverse of the species of Group 18 in the reply filed on August 22, 2005 is acknowledged. Applicants' arguments with respect to the rejoinder of the species of Groups 10 and 21 are convincing, and they have been re-joined and examined with the elected species.

With respect to the other species, the traversal is on the ground(s) that there would be no undue burden in examining all of the species. This is not found persuasive because as pointed out in the election of species requirement, the species are patentably distinct from one another, and the search of patentably distinct species would require multiple non-overlapping searches. This constitutes an undue burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 43. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 43 and 44 appear to be identical in scope. The only difference between the two claims is the terminology used to describe the amino acid positions which are being substituted; however, despite the difference in terminology, the same residues in Factor IXa are

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being substituted. See page 8, lines 19-23, of Applicants' specification for a discussion of the different numbering systems.

4. Claims 9, 38, 43, and 44 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent applications PCT/US97/08282 or of U.S. application serial no. 08/648,561 because the parent applications, under the test of 35 U.S.C. 112, first paragraph, do not disclose the specific muteins recited in claim 9, part (vii), or in claims 38, 43, and 44.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Fischer et al (U.S. Patent No. 6,034,222). Fischer et al teach pharmaceutical compositions comprising pro-Factor IX, which is used as a Factor IX antagonist. See, e.g., column 3, line 6 - column 4, line 2, and column 5, lines 13-23. Factor IX is a synonym for Christmas factor, and therefore Fischer et al's pro-Factor IX corresponds to Applicants' inactive Christmas factor.

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the Miyata et al article (British Journal of Haematology, Vol. 88, pages 156-165). The Miyata et al article teaches Factor IX Bm Kiryu, isolated and purified and in the form of a buffered saline solution. See page 157, column 1, last paragraph. Note that an intended use limitation, i.e. "pharmaceutical", does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

7. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the Sakai et al article (J. Biochem., Vol. 105, pages 756-759). The Sakai et al article teaches a Factor IX variant in which phenylalanine is present instead of the normal valine residue at position 182, which results

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in markedly reduced clotting activity. The Factor IX variant is isolated and purified and in the form of a buffered saline solution. See, e.g., the Abstract and page 757, column 1, fourth full paragraph. Factor IX is a synonym for Christmas factor, and therefore the Sakai et al article's Factor IX variant corresponds to Applicants' inactive Christmas factor. Note that an intended use limitation, i.e. "pharmaceutical", does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

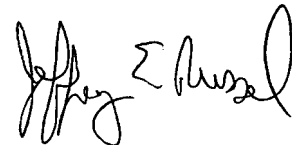
8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the Liebman abstract (Blood, Vol. 84, No. 10, Suppl. 1, page 66A, Abstract 253). The Liebman abstract teaches an isolated Gla-deficient Factor IX which acts as a Factor IX inhibitor. The Liebman abstract's Gla-deficient Factor IX corresponds to Applicants' des- $\gamma$ -carboxyl Factor IX. Note that an intended use limitation, i.e. "pharmaceutical", does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

9. Claims 38 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

January 23, 2006